

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

OPTRASCAN, INC.,)
)
Plaintiff,)
)
v.) C.A. No. 24-649-JLH
)
MORPHLE LABS, INC.,) JURY TRIAL DEMANDED
)
Defendant.)
)

FIRST AMENDED COMPLAINT

Plaintiff Optrascan, Inc. (“Optrascan”) files this First Amended Complaint for Patent Infringement against Defendant Morphle Labs Inc. (“Morphle” or “Defendant”) and alleges as follows:

NATURE OF LAWSUIT

1. This is a claim for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code.

THE PARTIES

2. Plaintiff Optrascan is a corporation having a principal place of business located in San Jose, California. Optrascan is the owner, by assignment, of U.S. Patent Number 10,338,365 (the '365 Patent) issued July 2, 2019, and entitled “Slide Storage, Retrieval, Transfer, and Scanning System for a Slide Scanner” (copy attached as Exhibit A) and U.S. Patent Number 10,586,376 (the '376 Patent) issued March 10, 2020, and entitled “Automated Method of Predicting Efficacy of Immunotherapy Approaches” (copy attached as Exhibit B). Optrascan owns all rights, title, and interest in, and has standing to sue for infringement of the '365 Patent and '376 Patent.

3. On information and belief, Defendant Morphle is in the business of providing microscope slide scanners. Morphle is incorporated in Delaware and has its principal place of business is in Bangalore, India, with a permanent address of 7th Main, 13th Cross, Indirangar 2nd Stage First Floor, No. 19, Bangalore, Karnataka, India 560038.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the patent laws of the United States of America, Title 35 U.S.C. This Court has jurisdiction over the subject matter of the Complaint under 28 U.S.C. §§ 1331 and 1338(a).

5. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), (c) and 1400(b), including because Morphle resides in Delaware as its state of incorporation.

6. The Court has personal jurisdiction over Morphle because it is incorporated within this District and has committed acts of direct and indirect infringement in this District, including through selling infringing products and services in this District.

THE SUBJECT PATENTS

7. The ‘365 Patent and ‘376 Patent are directed to techniques to retrieve, transfer and scan slides for analysis. Such a method of treatment finds particular value in analyzing slides, for example, pathology slides of sections of a tissue in an automated and in a time efficient manner with fidelity of the results maintained. The patented technology thus makes it simpler and quicker, with more consistent results than prior methods.

8. The ‘365 Patent is entitled, “Slide Storage, Retrieval, Transfer, and Scanning System for a Slide Scanner” and contains multiple claims directed to the automated scanning of slides, including those with pathology tissue sections. The ‘365 Patent was properly and duly

issued by the United States Patent and Trademark Office and the ‘365 Patent is presumed to be valid.

9. The ‘376 Patent is entitled, “Automated Method of Predicting Efficacy of Immunotherapy Approaches” and contains multiple claims directed to the automated scanning of slides, including those with pathology tissue sections. The ‘376 Patent was properly and duly issued by the United States Patent and Trademark Office and the ‘376 Patent is presumed to be valid.

FIRST CAUSE OF ACTION: INFRINGEMENT OF THE ‘365 PATENT

10. Optrascan restates and incorporates by reference paragraphs 1 through 9 above as if fully re-stated herein.

11. The inventors of the ‘365 Patent, Abhijeet Gholap, Anagha Jadhav, Isha Doshi and Somwanshi were the first to identify and put into practice the use of an automated slide storage, retrieval, transfer and scanning system of the type and form of the claimed invention. Abhijeet Gholap, Anagha Jadhav, Isha Doshi and Somwanshi have assigned their rights in the ‘365 Patent to Optrascan.

12. The inventors of the ‘365 Patent recognized inefficiencies in the systems and methods for the microscopic analysis of slides containing body fluids and tissue for determining the cause of disease. Conventionally, a pathologist performed microscopic examination of body fluid samples or biopsy tissue mounted on glass slides using an optical microscope for diagnosis in which the microscope slide would be loaded by hand. This conventional process was slow and time consuming, leading to the development of automated loading of slides as well as digital pathology, which converts microscope slides into high resolution, whole-slide digital images that can be viewed, managed, analyzed and interpreted with a computer instead of a microscope. The automated loading and digital pathology correspondingly led to the development of digital whole

slide scanners, which convert analog data on glass slides to digital images on computers for analysis.

13. While the market developed multiple options for digital whole slide scanners, they also have had their share of problems. For example, the scanners typically have small capacities and cannot be scaled to meet increased demands in efficiency and testing volumes. Having identified these drawbacks, the inventors of the ‘365 Patent created an inventive system for slide storage, retrieval, and transfer for slide scanning that is robust automated, accurate, simple to use, and low cost. The inventive system can also pick up slides of various thicknesses, hold them securely during the scanning process, and deposit them back into slide storage once the scanning is complete.

14. The Defendant, despite being advised by Optrascan of the ‘365 Patent and its infringing activities, has nevertheless continued to make, use, and sell slide readers that infringe the inventive system of the ‘365 Patent. In particular, Defendant was informed of their infringing activity in writing no later than November 17, 2022, by Optrascan. Despite the written notice, Defendant has continued to undertake activities, including offering for sale and selling slide readers that infringe the two patents-in-suit. These offers for sale and sales have been made throughout the United States and include offer for sale and sales of the infringing slide readers in Delaware. Defendant has continued to infringe the ‘365 Patent (Exhibit C – Infringement Claim Chart ‘365 Patent) as Defendant is well aware of the significant benefits provided by Optrascan’s patented technology to Defendant’s infringing slide readers.

15. For example, the Defendant’s MorphoLens 240 is a slide scanner meeting all of the limitations of at least claim 1 of the ’365 Patent. As explained in Exhibit C, the MorphoLens

240 includes carriers (i.e., “slide basket”) for storing a plurality of slides and a rack (i.e., “slide storage assembly”) for storing the carriers.



MorphoLens 240

A high throughput workhorse with integrated image storage, LIMS integrations & AI workflows - all baked in.

[Get Instant Quote >](#) [Get Brochure >](#)

Scanner Specifications

Slide Rack

- 240 slide batch at once
- 40 carriers with 6 slides per carrier
- Supports continuous loading

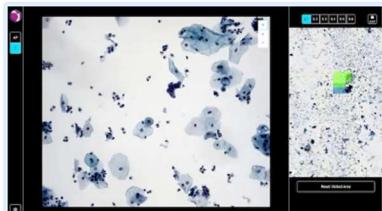
<https://www.morphlelabs.com/products/morpholens-240-scanner>. The demo video provided at <https://www.morphlelabs.com/products/morpholens-240-scanner> further displays and demonstrates a rack (i.e., “slide storage assembly”) configured to store at least one carrier (i.e., “slide basket”) in which each carrier is configured to store a plurality of slides. *See* demo video at 0:17-0:28 and 0:58-1:02.

16. The demo video for the MorphoLens 240 at, e.g., 0:30 to 0:41, (<https://www.morphlelabs.com/products/morpholens-240-scanner>; https://www.youtube.com/watch?v=062JnDp_yb8&list=PL1MF6lDFhBJyG5i0-Gi9ff-v6K9ZCer1j&t=3s) displays and demonstrates a slide scanning stage configured to receive a slide into a slide holder below a microscope objective in order to scan the slide.



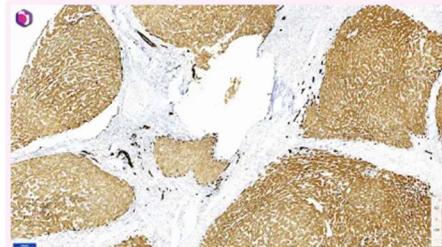
17. The MorphoLens 240 web page

(<https://www.morphlelabs.com/products/morpholens-240-scanner>) also describes how the device scans the slide under a microscope objective, as highlighted in the screenshots below.



#1 - Live Microscopy mode with continuous Z-stack

[Watch Video >](#)



#2 - Whole Slide Imaging (WSI)

[Watch Video >](#) [Access Sample Scans >](#)

Uses dual objective switching system where

- 4X objective does an initial whole slide scan and serves as a navigation map
- 40X objective is used to fetch real-time images as the remote user navigates across 4X preview scan

Offers 2 focusing modes

- Continuous Focus for Tissue section slides (recommended for Frozen Section remote reporting)
- Continuous Z-stack for Cytology smear slides (recommended for any slide with overlapping cells)

Live microscopy is preferred over other modes where one needs the ability to start the diagnosis immediately after slide preparation

The classical scanning mode where the variation of a focal plane if any is pre-calculated with a focus map and later the motorized XY stage captures optimally focused images by translating across the region of the scanning.

Uses single 40X or 20X objective combined with a secondary overhead camera for capturing preview (thumbnail) of the full slide including the barcode area.

Whole slide imaging is preferred over other modes when exhaustive image capture is needed for deferred access.



#3 - Volume Scanning

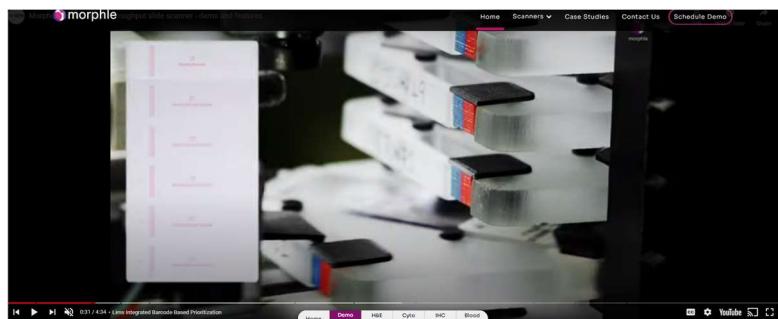
[Access Sample Scans >](#)

An all powerful scanning mode where multiple images covering **all focal planes** are captured at every field. The end result is essentially a whole slide scan mixed with pre-captured Z-stack at every position.

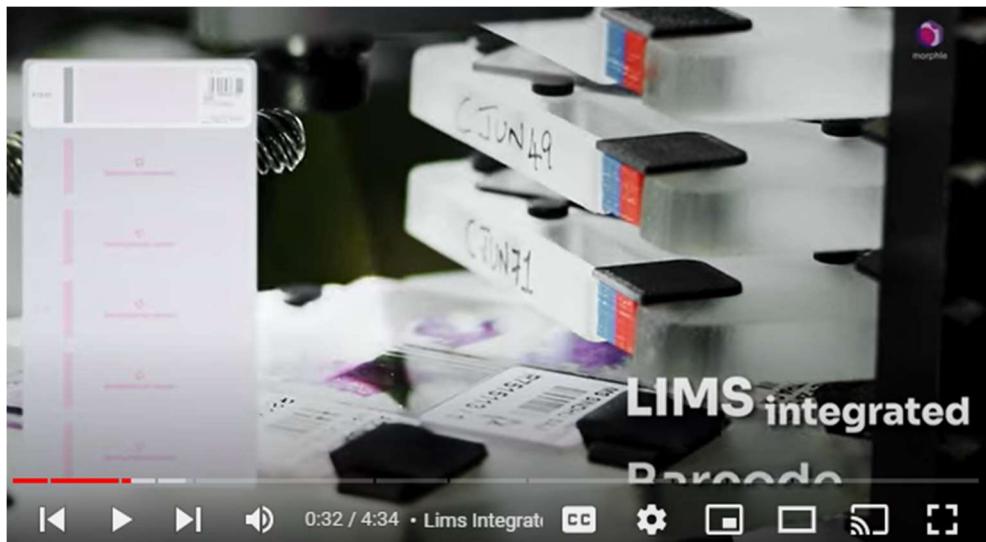
Similar to WSI mode, Volume scanning uses a **single 40X or 20X** objective combined with a secondary overhead camera for capturing preview (thumbnail) of the full slide including the barcode area.

Volume scanning is **preferred over WSI** when exhaustive image capture is needed for **slides with overlapping cells** such as Fine Needle Aspiration Biopsy slides, Pap smear slides etc.

18. The demo video provided at <https://www.morphelabs.com/products/morpholens-240-scanner> also explains how each of the remaining components of claim 1 are present in the MorphoLens 240. As shown in the demo video, the MorphoLens 240 includes a slide basket transfer assembly configured to retrieve and store at least one side basket from and into the slide storage assembly. *See, e.g.*, demo video at 0:30-0:35. The slide basket transfer assembly retrieves a carrier (i.e., “slide basket”) for scanning by a slide scanner as shown in the screen shots below taken from the demo video.



19. The demo video also shows that the MorphoLens 240 includes a slide transfer assembly that retrieves a slide from the slide basket transfer assembly, delivers the slide to the slide scanning stage of the slide scanner, and returns the slide from the slide scanning stage to the slide basket transfer assembly. See, e.g., demo video at 0:30-0:35.





For example, as the lead screw (shown in the top left portion of the above screen shots) of the slide transfer assembly turns, an individual slide is translated beneath a slide scanner. Either literally or under the doctrine of equivalents, on information and belief, the slide is returned to the slide basket transfer assembly after scanning by the slide scanner. On information and belief, for the MorphoLens 240 to move the slide back to the slide storage assembly after being positioned at the slide scanner for scanning, the slide must be returned to the slide basket transfer assembly, which is responsible for storing the slide basket that holds the scanned slide into the slide storage assembly.

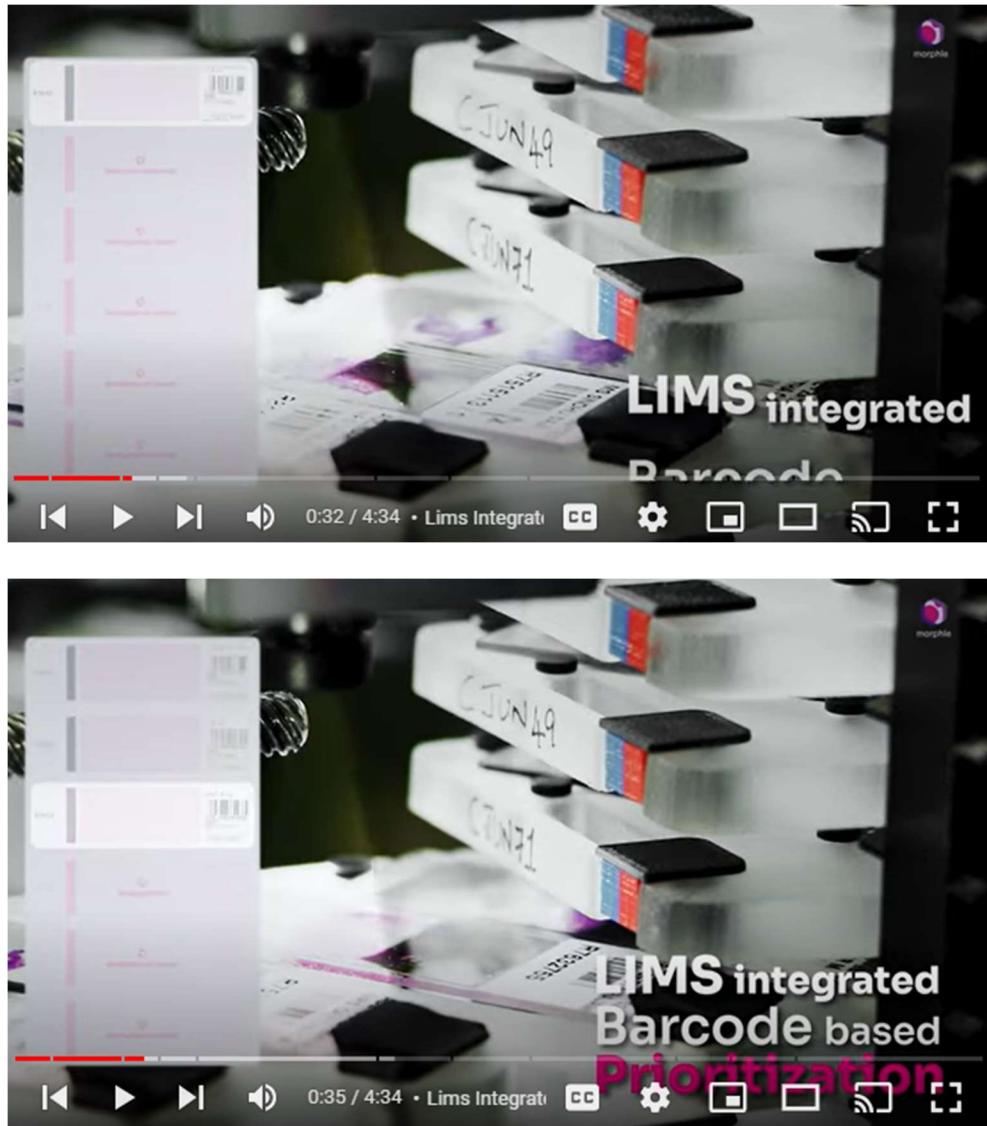
20. In addition, the portions of the MorphoLens 240 that retrieve and return slide baskets to the storage assembly and that retrieve and deliver slides for scanning and return them to the portion that retrieves and returns slides baskets to the storage assembly perform the same functions as the slide basket transfer assembly and the slide transfer assembly in substantially the same way to achieve the same result. Accordingly, these portions of the MorphoLens 240 at least meet the slide basket transfer assembly and the slide transfer assembly under the doctrine of equivalents.

21. Further, as shown in the demo video, the MorphoLens 240 includes a slide basket holder of the slide basket transfer assembly that moves vertically along a Z axis to transfer a carrier (i.e., “slide basket”) from the slide storage assembly to the slide transfer assembly. *See, e.g.*, demo video at 0:29-0:35. On information and belief, to be able to retrieve and scan each slide basket in the slide storage assembly in the MorphoLens 240, the slide basket holder of the slide basket transfer assembly must move on the vertical Z axis to retrieve and scan the other slide baskets and provide the retrieved slide baskets to the slide transfer assembly. The slide basket holder is integral with the slide basket transfer assembly as shown in the demo video and screen shot below:



22. A support base of this slide transfer assembly moves horizontally in an X-Y plane in order to transfer a slide from the slide basket transfer assembly to the slide scanning stage of the slide scanner. *See id* at 0:29-0:34. The demo video also displays and demonstrates a slide basket holder of the slide basket transfer assembly being configured to move vertically along a Z axis in order to transfer a slide basket from the slide storage assembly to the slide transfer assembly. *See id.* On information and belief, to be able to retrieve and scan each slide basket in the slide storage assembly in the MorphoLens 240, the slide basket holder of the slide basket transfer assembly must move on the vertical Z axis to retrieve and scan the other slide baskets. As shown in the

Demo video at, for example, 0:29-0:34, the support base of the slide transfer assembly in the MorphoLens 240 moves horizontally in an X-Y plane that is perpendicular to the Z axis to transfer the slide from the slide basket transfer assembly to the slide scanning stage, as shown in the screens shots below:



The MorphoLens 240 thus meets all of the limitations of at least claim 1 of the '365 patent and is therefore infringing.

23. Despite knowing that the inventive patented technology provided significant benefits to Defendant's slide reader, including the MorphoLens 6, MorphoLens 240, and

Hemolens, Defendant has decided to proceed with using the inventive technology without obtaining the consent of Optrascan. Instead, Defendant, with full knowledge of the ‘365 Patent’s existence, has willfully infringed the ‘365 Patent to the great detriment and loss of Optrascan.

24. Defendant has been on notice of the ‘365 Patent and Optrascan’s claims of infringement, and, for at least this reason, Defendant’s actions are believed to be willful and undertaken with the intent to infringe the ‘365 Patent.

25. Defendant’s direct infringement and inducement to infringe have been willful and have deliberately injured and will continue to injure Optrascan unless and until the Court enters an injunction prohibiting further infringement and, specifically, enjoining further use, sale and/or offer for sale of the patented method that fall within the scope of the ‘365 Patent’s claims.

SECOND CAUSE OF ACTION: INFRINGEMENT OF THE ‘376 PATENT

26. Optrascan restates and incorporates by reference paragraphs 1 through 21 above as if fully re-stated herein.

27. The inventors of the ‘376 Patent, Abhijeet Gholap, Anagha Jadhav and Gurunath Kamble were the first to identify and put into practice the use of an automated method to predict the efficacy of an immunotherapy treatment of the type and form of the claimed invention. Abhijeet Gholap, Anagha Jadhav and Gurunath Kamble have assigned their rights in the ‘376 Patent to Optrascan.

28. The ‘376 Patent relates to an innovative consolidated system for whole slide scanning of biological specimens, image acquisition, image management, and image analysis to detect histological and immunohistochemical biomarkers. In contrast to conventional systems that require separate devices and processes to perform these functions, the inventive system of the ‘376 Patent provides a fully automated analytics application that is integrated into a slide scanner as the

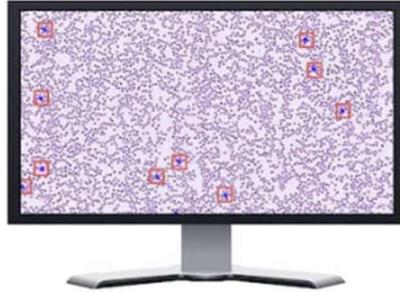
slide is being scanned without using third party software. The inventive system also works on a whole slide image or with registered images stained with multiple biomarkers to facilitate 2D reconstruction and analytics. It can also work on serial sections yielding multiple whole slide images to facilitate 3D reconstruction and analytics. As a result, the ‘376 Patent provides a system that aids pathologists to draw improved and more accurate diagnoses of the applicable pathological condition.

29. The ‘376 Patent addresses a long-standing need in the art by providing an integrated system that performs advanced image processing and analytics, thereby aiding pathologists in accurately diagnosing various diseases. As described in the specification, embodiments of the invention, “support[] whole slide scanning, registration, segmentation and quantification of cancer cells based on biomarker content, thus opening the pathways to aid immuno oncology development.” ‘376 Patent at 2:3-7. The scanning, registration, segmentation and quantification of cells described and claimed in the ‘376 Patent represent significant advances over prior art systems and manual analysis. For example, claim 1 of the ‘376 Patent describes, in part, automatically “analyzing the plurality of cells with at least one cell classification algorithm through the processing device in order to identify a tumor cell percent positivity value and an immune cell percent positivity value” and “calculating a treatment efficacy score from the tumor cell percent positivity value and the immune cell percent positivity value,” which may significantly improve the speed and accuracy of disease diagnosis. These elements of claim 1 also provide a significant technical improvement that improves accuracy, provides consistency, and overcomes problems in prior art manual-based analysis. *See* ’367 Patent at 2:43-49. As another example, claims 4, 10, 11 and 12 of the ‘376 Patent describe various techniques for processing images of samples that cannot be performed manually and that represent a significant improvement over the

state of the art. The improvements of the ‘376 Patent were not well-understood, routine, or conventional at the time of filing the ‘376 Patent.

30. The Defendant, despite being advised by Optrascan of the ‘376 Patent and its infringing activities, has nevertheless continued to make, use, and sell slide readers that infringe the inventive system of the ‘376 Patent. In particular, Defendant was informed of their infringing activity in writing no later than November 17, 2022, by Optrascan. Despite the written notice, Defendant has continued to undertake activities, including offering for sale and selling slide readers that infringe the two patents-in-suit. These offers for sale and sales have been made throughout the United States and include offer for sale and sales of the infringing slide readers in Delaware. Defendant has continued to infringe the ‘376 Patent (Exhibit D – Infringement Claim Chart ‘376 Patent) as Defendant is well aware of the significant benefits provided by Optrascan’s patented technology to Defendant’s infringing slide readers.

31. For example, the Defendant’s HemoLens 16 product is a slide scanner meeting all of the limitations of at least claim 1 of the ‘376 Patent. As explained in Exhibit D, the HemoLens 16 product is an automated slide scanning system having an image acquisition unit electronically connected to a processing device. The HemoLens 16 product includes an automated slide scanning system (e.g., “Auto-scan”) having an image acquisition unit (e.g., “2 Objectives” and “Preview Camera”) and is electrically connected to a processing device (e.g., “local GPU”) that performs processing and analysis including Cell Differentiation.



1 Walk-away Scanning by the technician

- Auto monolayer / feather-edge detection.
- Auto Oil dispensing.
- Auto-cell detection + Multi-objective scanning.

2 AI-enabled Cell Differentiation

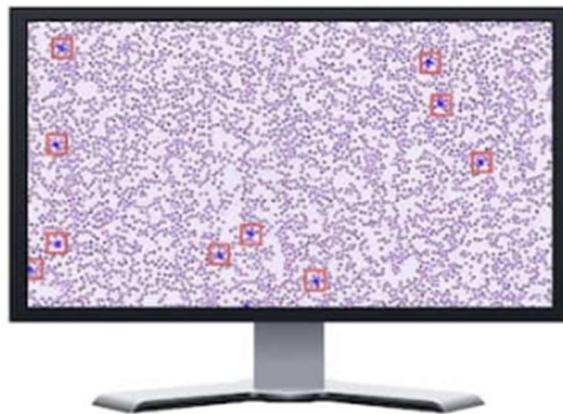
- 120 WBCs are classified, sorted & flagged.
- No cloud upload needed. AI runs on the local GPU.

Optical Setup	Robotic turret with 2 Objectives a. 100x oil immersion b. 40x dry High power flash LED & Condenser optimized for multiple NAs
Image Resolution	Large size 2nd gen sony sensors yield a. 0.08 microns / pixel @ 100x b. 0.22 microns / pixel @ 40x Secondary Preview Camera for single shot quick view of slide
Scan Algorithm	Steps within Auto-scan <ul style="list-style-type: none"> → Single shot capture with Preview camera → WSI @ 40x for AI determined boxed area → Switch to 100x & Auto Oil dispensing → 100x scan for AI-determined ROIs

<https://www.morphlelabs.com/products/hemolens>. The HemoLens 16 product also receives a sample slide through the automated slide scanning system in which a tissue sample is mounted to the sample slide and acquires at least one slide image of the tissue sample through the image acquisition unit, as also shown in the above screen shots. As explained in these screen shots and on the product website, the HemoLens 16 product includes the ability to automatically scan up to

16 slides having tissue samples for analysis using objectives and cameras to produce slide images of the slides with the tissue samples.

32. In addition, the HemoLens product website executes at least one cell segmentation process on the slide image through the processing device in order to identify a plurality of cells from the slide image. The cell segmentation process is shown, for example, by Cell Differentiation processing in the HemoLens 16 product that can classify, sort, and flag cells, as shown in the screen shots below.



2 AI-enabled Cell Differentiation

- 120 WBCs are classified, sorted & flagged.
- No cloud upload needed. AI runs on the local GPU.

- Accurate pre-bucketed WBCs across classes for quick flagging
- Proven to speedup the review process by 10x



- Pick specific etiologies from RBC morphometric parameters
- Filter based on diameters to hunt for microcytic and macrocytic anemias
- Sort cells based on elongation to quickly detect sickle cells
- Surface irregularity based sorting to check for Poikilocytosis

- Hunt for abnormal Platelets based on filtering & sorting across morphometric parameters
- Platelet sorting to check for myeloproliferative or myelodysplastic syndromes
- Order platelets by size to hunt for macrothrombocytopenia



<https://www.morphlelabs.com/products/hemolens>.

33. These screen shots and the product website also show that the HemoLens 16 product analyzes a plurality of cells with at least one cell classification algorithm through the processing device in order to identify a tumor cell percent positivity value and an immune cell percent positivity value. For example, while performing Cell Differentiation, the HemoLens 16 product can identify a variety of abnormal cells including at least anemias, sickle cells, poikilocytosis, myeloproliferative syndrome, myelodysplastic syndrome, and macrothrombocytopenia. On information and belief, whether literally or under the doctrine of equivalents, the identification of abnormal cells includes identification of tumor cells. The Cell Differentiation can also identify immune cells such as lymphocytes and white blood cells. In

addition, as shown in the screen shots below, the HemoLens 16 product provides information about the identified cells including percentages of each type, which necessarily includes a tumor cell percent positivity value and an immune cell percent positivity value.



<https://www.morphlelabs.com/products/hemolens>.

34. Finally, the HemoLens 16 is also configured to calculate a treatment efficacy score from the tumor cell percent positivity value and the immune cell percent positivity value. On information and belief, whether literally or under the doctrine of equivalents, the HemoLens 16 can provide a preliminary report that includes a treatment efficacy score or its equivalent based on the results of Cell Differentiation including the tumor cell percent positivity value and the

immune cell percent positivity value when provided with additional information including, for example, counter values, clinical investigation, and/or patient demographics.

35. In addition, the MorphoLens 240 is another slide scanner meeting all of the limitations of at least claim 1 of the ‘376 Patent as explained in Exhibit E.

36. Despite knowing that the inventive patented technology provided significant benefits to Defendant’s slide reader products, including the MorphoLens 6, MorphoLens 240 and Hemolens, Defendant has decided to proceed with using the inventive technology without obtaining the consent of Optrascan. Instead, Defendant, with full knowledge of the ‘376 Patent’s existence, has willfully infringed the ‘376 Patent to the great detriment and loss of Optrascan.

37. Defendant has been on notice of the ‘376 Patent and Optrascan’s claims of infringement, and, for at least this reason, Defendant’s actions are believed to be willful and undertaken with the intent to infringe the ‘376 Patent.

38. Defendant’s direct infringement and inducement to infringe have been willful and have deliberately injured and will continue to injure Optrascan unless and until the Court enters an injunction prohibiting further infringement and, specifically, enjoining further use, sale and/or offer for sale of the patented method that fall within the scope of the ‘376 Patent’s claims.

PRAYER FOR RELIEF

WHEREFORE, Optrascan asks this Court to enter judgment against Defendant and against its subsidiaries, affiliates, agents, servants, employees and all persons in active concert or participation with them, granting the following relief:

A. An award of damages adequate to compensate Optrascan for the infringement that has occurred, together with prejudgment interest from the date infringement of the ‘365 Patent and ‘376 Patent began;

- B. Increased damages as permitted under 35 U.S.C. § 284;
- C. A finding that this case is exceptional and an award to Optrascan of its attorneys' fees and costs as may be appropriate and as provided by 35 U.S.C. § 285;
- D. A permanent injunction prohibiting further infringement, inducement and contributory infringement of the '365 Patent and '376 Patent.
- E. Pre-judgment interest calculated from the time of the first occurrence of any infringing activity through and until entry of judgment; and
- F. Such other and further relief as this Court or a jury may deem proper and just.

JURY DEMAND

Optrascan demands a trial by jury on all issues presented in this Complaint.

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